Seven-Year Follow-Up Results of TiUnite Implants Supporting Mandibular Overdentures: Early versus Delayed Loading

Ilser Turkyilmaz, DDS, PhD;* Tolga F. Tozum, DDS, PhD;† Dana M. Fuhrmann, DDS;‡ Celal Tumer, DDS, PhD§

ABSTRACT

Background and Purpose: Implant-supported mandibular overdentures have recently become a popular treatment alternative for edentulous patients desiring increased retention of complete dentures. The goal of this study was to evaluate and present treatment outcomes of mandibular overdentures retained by two unsplinted, early-loaded implants and compare these results with those for delayed-loaded implants.

Material and Methods: Twenty-six edentulous patients had two interforaminal implants placed with a one-stage protocol. The patients were each treated with a mandibular overdenture supported by ball abutments. In the test group, the overdenture was loaded 1 week after surgery and in the control group, the overdenture was loaded 3 months after surgery. Standardized clinical and radiographic parameters were recorded at surgery, and after 3, 6, 12, and 18 months, and 2, 3, 4, 5, and 7 years.

Results: Because two patients did not make the 7-year recall, only 24 patients (48 implants) were evaluated in this study. No implants were lost, and 1.31 ± 0.2 mm marginal bone resorption was noted for all implants after 7 years. Implant stability measurements, clinical peri-implant parameters and marginal bone levels exhibited no statistically significant differences between the two groups over 7 years.

Conclusion: The results of this clinical trial show that there is no significant difference in the clinical and radiographic outcomes of patients treated with mandibular overdentures supported by TiUnite implants that are either early or delayed loaded.

KEY WORDS: early loading, implant, mandible, overdentures, RFA, stability

INTRODUCTION

Removable complete dentures have been a traditional way to restore edentulous patients for many years. However, bone resorption of residual ridges over time and decreased denture retention and stability are continual concerns for both practitioners and patients.[1–3] Edentulism is also associated with decreased masticatory efficiency, which affects overall nutritional intake and patient health.[4,5] Conventional denture dissatisfaction may be further compounded by poor neuromuscular control, diminished oral sensory function, and low salivary flow.[6,7] These limitations often cause social, psychological, and functional disabilities.

Patients more commonly report problems with the mandibular denture than the maxillary denture. The anatomical disadvantages of the mandible have led to focus on improving treatment protocols and prosthetic design for this arch. The McGill Consensus statement in 2002 concluded that a two-implant-retained overdenture is now the standard of care for the edentulous mandible.[8] Multiple studies have shown that this treatment modality successfully provides increased denture retention resulting in higher patient satisfaction.[9–11]

*Assistant professor, Prosthodontics, Department of Comprehensive Dentistry, Dental School, University of Texas Health Science Center, San Antonio, TX, USA; †associate professor, Department of Periodontology, Faculty of Dentistry, Hacettepe University, Ankara, Turkey; ‡resident in prosthodontics, Department of Comprehensive Dentistry, Dental School, University of Texas Health Science Center, San Antonio, TX, USA; §professor, Dean, Faculty of Dentistry, Hacettepe University, Ankara, Turkey

Reprint requests: Dr. Ilser Turkyilmaz, Department of Comprehensive Dentistry, Dental School, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, MSC 7912, San Antonio, TX 78229-3900, USA; e-mail: turkyilmaz@uthscsa.edu

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Additionally, the success rate of dental implants restored by this modality have shown to be high, regardless of whether the implants were splinted or unsplinted.[12–14]

Because Brånemark developed the use of dental implants to replace missing teeth in the 1980s, there have been many advances in implant surface characteristics (i.e., thermal oxidation, plasma spraying, grit blasting, acid etching) and implant design (parallel-wall implants, tapered implants). These improvements have initiated immediate and early loading protocols for dental implants.[15–18]

Implant loading can be classified into three types: (1) immediate loading, in which the prosthesis is attached the day of implant placement; (2) early loading, in which the prosthesis is attached at a second procedure, anytime prior to traditional loading at 3–6 months; and (3) delayed loading, in which the prosthesis is attached after the conventional 3–6 months of healing.[19]

Immediate and early loading protocols often involve the use of one-stage implant treatment, using non-submerged implants,[20] or a two-stage implant with a healing abutment.[21,22] The advantages of the one-stage implant surgical protocol are: one surgical intervention for the patient, reduced treatment time and cost, and clinical monitoring of implant stability during osseointegration.

Several studies have reviewed immediate or early loading protocols for splinted implants supporting mandibular overdentures.[23,24] However, only a few studies have reviewed the long-term outcomes of immediate and early loading of unsplinted implants supporting mandibular overdentures.[25–27] The purpose of this prospective clinical trial was to compare the clinical performance of early- and delayed-loaded dental implants supporting mandibular overdentures and present 7-year outcomes of these implants.

MATERIALS AND METHODS

The present clinical trial was carried out in accordance with the Declaration of Helsinki. Each patient received oral and written information about the study and provided informed consent. The study protocol was approved by the Ethics Committee of Hacettepe University, Ankara, Turkey. Twenty-six edentulous patients with chronic problems related to their mandibular complete dentures were enrolled in this study in 2003. All implants were placed, and all dentures (maxillary complete and mandibular overdentures) were delivered by one clinician (I.T.) at the Dental School, Hacettepe University. The two authors (I.T. and T.T.) followed these patients for 2 years at Hacettepe University. Then, the same two authors followed up these patients up to 5 years at either the university or in private practice. Seven-year follow-up was performed by two authors (I.T. and T.T.) at a private practice in Ankara in June 2010. Because two patients were not able to make this follow-up as they were on vacation, 7-year results were collected from only 24 patients with 48 implants. Two patients who missed this follow-up were contacted by phone, and they informed us that they did not have any problem with their implants and overdentures.

Adequate bone volume in the anterior mandible for placement of 3.75×15-mm implants and consistent complaints with existing mandibular dentures were considered as the inclusion criteria. Uncontrolled systemic disease that might compromise implant surgery, previous bone augmentation, and fresh extraction sockets in the anterior region of the mandible were considered as exclusion criteria. For presurgical clinical assessment of each mandible, panoramic radiographs (Planmeca OY, Helsinki, Finland) and computerized tomography (Siemens AR-SP 40, Munich, Germany) were used.

Surgical and Prosthodontic Procedures

The surgical protocol was consistent among the test and control groups. Each patient received local anesthesia and a midcrestal incision was made in the anterior mandible. Mucoperiosteal flaps were elevated and the alveolar crest was reduced if necessary to obtain a flat bony base. Two interforaminal implants (3.75×15 mm, TiUnite, MK III, Nobel Biocare AB, Göteborg, Sweden) were placed in the canine areas of each mandible using the manufacturer's protocol.

Patients were randomly assigned into one of two groups:

Test group (Group T): Baseline resonance frequency (RF) measurements were made at the implant level and ball abutments (3 mm, Nobel Biocare AB, Göteborg, Sweden) were immediately seated on the implants (Figure 1). The mucoperiosteal flaps were sutured and patients followed a soft diet for 1 week. Five days after surgery, preliminary impressions were made using irreversible hydrocolloid (Cavex, CA37, Haarlem, Netherland) and study casts were fabricated. Final impressions were made with a custom-made acrylic resin tray using

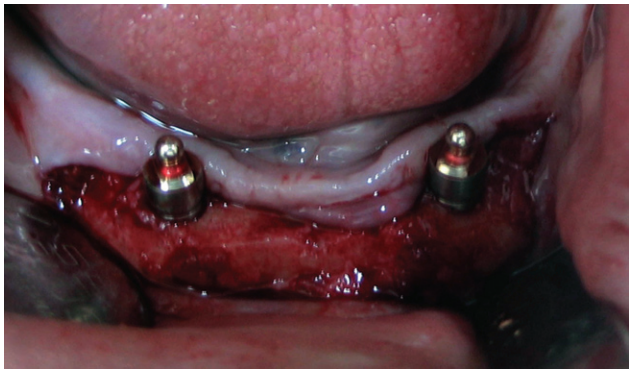

Figure 1 The ball attachments were seated immediately after the implant placement in the test group.

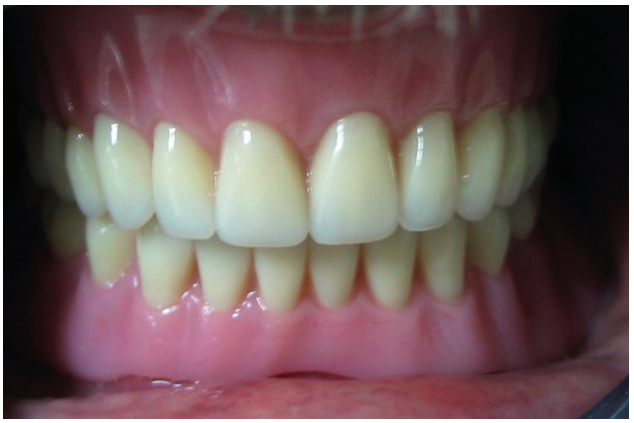

Figure 3 Intraoral view of the patient with both dentures in place.

silicone impression material (Coltex® Medium, Coltene/Whaledent AG, Altstatten, Switzerland). Master casts were poured (Moldano, Bayern, Leverrusen, Germany) using ball abutment replicas seated in the master impression. Maxillary and mandibular base plates and occlusion rims were made and used for maxillomandibular jaw relation records. The maxillary and mandibular casts were mounted, denture teeth were set-up (Major Dent, Moncalieri, Italy) and aesthetics, phonetics, and occlusion were evaluated and adjusted as necessary. A single technician processed all of the prostheses using heat-polymerized acrylic resin (Meliodent, Heraeus Kulzer Ltd, Newbury, Germany). The maxillary complete dentures and the mandibular overdentures, with respective gold caps, were delivered to the patients 7 days after surgery (Figures 2 and 3).

In the control group (Group C), baseline RF measurements were made at the implant level, healing abutments were placed on the implants and the mucoperiosteal flaps were then sutured. One week after surgery, the new maxillary and mandibular complete dentures were delivered, following the same clinical steps as the test group. However, particular care was taken to ensure that the mandibular complete denture did not contact the healing abutments. Three months after implant placement, the healing abutments were replaced with ball abutments (3 mm, Nobel Biocare AB, Göteborg, Sweden). A reline impression was made, and the mandibular complete denture was converted to an implant-supported mandibular overdenture with a laboratory-processed hard reline procedure.

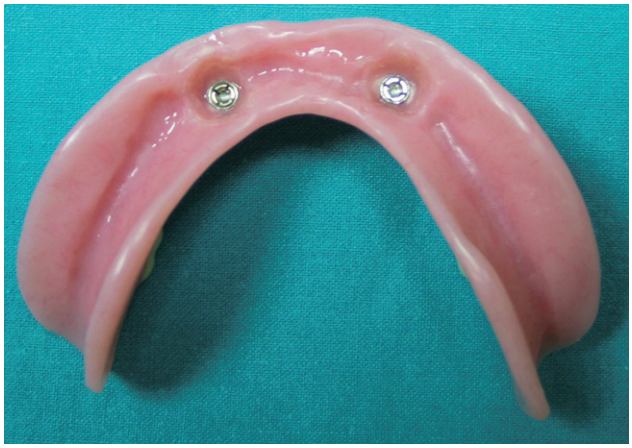

Figure 2 Tissue surface of mandibular overdenture with gold caps.

Follow Up

Implant Stability Evaluation. Implant stability was monitored by a RF analysis (RFA) technique (Osstell, Integration Diagnostics AB, Göteborg, Sweden). An RFA measurement produces an implant stability quotient (ISQ) unit for each implant, which is derived from the stiffness of the implant/bone complex. These ISQ units range from 0 to 100 based on the stability of the implant in the bone. High ISQ value indicates high stability, whereas low value indicates a low implant stability. In this study, all RFA measurements were made with a L-shaped transducer at the implant level (Figure 4) and were performed at the time of implant surgery and after 3, 6, 12, and 18 months and 2, 3, 4,5, and 7 years.

Radiographic Evaluation. Marginal bone levels around the implants were monitored with standardized intraoral periapical radiographs using a paralleling technique, which was clearly defined by Payne et al.[28] All

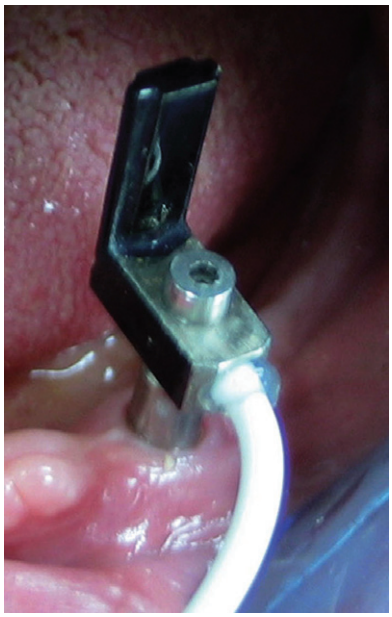

Figure 4 Clinically implant-level resonance frequency analysis measurement.

radiographs were scanned and analyzed, by one examiner, using image analysis software. Marginal bone resorption was measured using the implant-abutment interface as a reference point and the distance between two threads of the implant (0.6 mm) for calibration of those measurements. Radiographs were made at the time of implant placement, and after 6, 12, and 18 months and 2, 3, 4, 5, and 7 years.

Peri-implant Evaluation. Each implant site was clinically evaluated using the following parameters: The peri-implant plaque index (PI) quantified the plaque present around all abutments at or below the crest of the peri-implant mucosa using a modified Silness and Löe technique.[29,30] The peri-implant bleeding index (BI) measured the presence or absence of gingival bleeding using a modified Muhlemann and Son sulcus BI.[30,31] Peri-implant probing depths (PD) were measured at the mid-mesial, mid-distal, mid-buccal, and mid-lingual of each implant, making certain that the standardized probe and the long axis of the abutment were parallel. Finally, the gingival index (GI) reviewed the presence or absence of inflammation of the soft tissue around the same four sites of each implant.[29]

These peri-implant factors were recorded at follow-up visits of 1, 6, 12, and 18 months, and 2, 3, 4, 5, and 7 years after the implant surgery. Each implant received one averaged value for each parameter (PI, PD, BI, and GI).

Statistical Analysis

All of the statistical analysis was completed using Statistical Package for the Social Sciences (SPSS) statistical software (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test indicated that the distribution of data was nonparametric. The Mann–Whitney *U*-test was used to compare marginal bone loss, implant stability, and peri-implant (PI, PD, BI, GI) values between the two groups. $P < 0.05$ was considered statistically significant.

RESULTS

Twenty-six patients (14 females, 12 males), whose ages were 50–76 years (mean age 63 years) were initially included in this study. The mean age of the patients in Group T and C were 62.3 ± 8 and 63.2 ± 7, respectively, at implant placement. Postoperative recovery was uneventful for all patients. Two patients did not make this follow-up because they were on vacation; therefore, 7-year results were collected from only 24 patients with 48 implants. Two patients who missed this follow-up were contacted by phone, and they informed us that they did not have any problem with their implants and overdentures.

Radiographic Parameters

There were no implants failures after 7 years, giving a success rate of 100% (Figure 5). The test and control groups had 1.29 ± 0.2 mm (ranging from 1.01 to 1.48 mm), and 1.33 ± 0.2 mm (ranging from 1.12 to 1.53 mm) of marginal bone loss, respectively (Table 1), with an average of 1.31 ± 0.2 for both groups. There is no statistically significant difference between the two groups over 7 years ($p > 0.05$).

Implant Stability Parameters

The ISQ values for the test group was 74.9 ± 3.8 at the time of surgery and 74.1 ± 3.0 at the 7-year follow-up.

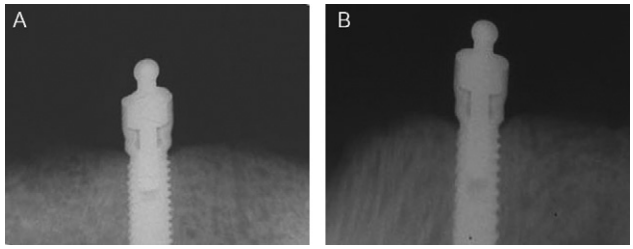

Figure 5 Periapical radiograph of the right (A) and left (B) implants with ball abutments after 7 years.

TABLE 1 Average Marginal Bone Levels from Implant Platform to the First Bone-Implant Contact (mm ± SD) During 7 Years

Groups	Surgery	Month 6	Year 1	Year 2	Year 3	Year 4	Year 5	Year 7
Group T	0.7 ± 0.3	0.85 ± 0.3	0.97 ± 0.3	1.13 ± 0.3	1.25 ± 0.2	1.44 ± 0.2	1.61 ± 0.3	1.99 ± 0.3
Group C	0.63 ± 0.2	0.82 ± 0.2	0.91 ± 0.3	1.11 ± 0.3	1.26 ± 0.3	1.42 ± 0.3	1.57 ± 0.2	1.96 ± 0.3

The control group had mean ISQ values of 75 ± 4.5 and 73.6 ± 2.0 at the time of surgery and 7-year follow-ups, respectively. There were no spastically significant differences ($p > 0.05$) between the two groups at any follow-up period (Figure 6).

Peri-Implant Paramaters

Table 2 shows the mean PI, PD, BI, and GI values over 7 years. The values in all four categories decreased from the time of surgery to month 18, then increased from 18 months to year 7, which are considered normal. None of the implants showed an ongoing peri-implantitis during the follow-up period. However, even with the change in values, there were no statistically significant differences between the two groups during the 7 years ($p > 0.05$).

DISCUSSION

The success criteria for the implants were: no radiolucencies, no mobility, and no signs of infection or pathology. In this study, the implant success rate for both groups was 100%, indicating that an unsplinted, two-implant-supported overdenture may be a successful treatment option for many patients. In addition, the single-stage surgery and shortened treatment time provide a treatment alternative that is optimal for the elderly edentulous patient. Other studies have shown excellent long-term success rates with mandibular 2-implant overdenture treatment. Vercruyssen et al.,[32] recently showed a 96% implant success rate over 25 years of patient follow-up visits for both splinted and unsplinted designs. The lower survival percentage, as compared with this study, may have resulted from the use of Brånemark machined implants (over 95% of the implants placed) and including patients that were smokers. However, this analysis still shows promising long-term results for mandibular two-implant overdentures. Marzola et al.,[33] treated 17 completely edentulous patients with immediately loaded, two-implant mandibular overdentures. The implants were unsplinted with ball abutments. After 1 year of follow-up, no implants were lost, resulting in 100% survival. The radiographic bone loss was measured and calibrated using digital analysis software and after 1 year was found to be 0.7 mm ± 0.5 mm. The author concluded that the immediately loaded, two-implant mandibular overdenture has been shown to be a positive treatment option. Payne et al.,[34] treated 24 completely edentulous patients with maxillary complete dentures and mandibular unsplinted, two-implant overdentures. Patients were allocated into two groups; one receiving Southern

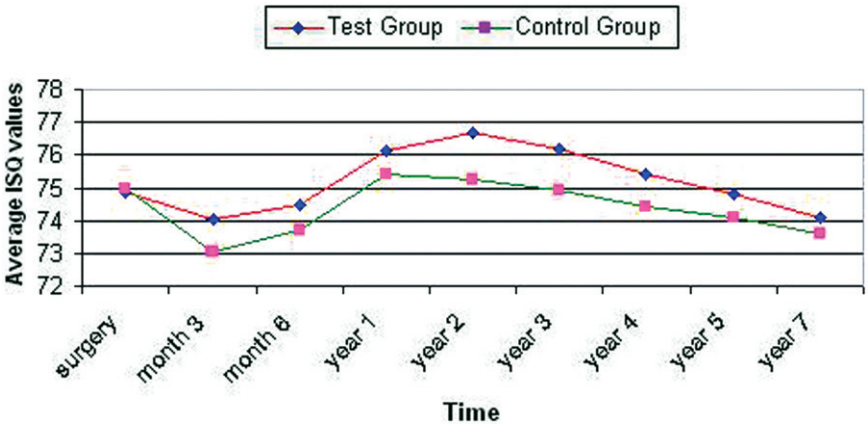

Figure 6 Average Implant Stability Quotient values during 7 years.

TABLE 2 Average Values (± SD) of Peri-Implant Soft Tissue Parameters during 7 Years

Parameters	Groups	Month 1	Month 6	Year 1	Year 2	Year 3	Year 4	Year 5	Year 7
PI	Group T	1.1 ± 0.9	0.85 ± 0.9	0.8 ± 1	0.89 ± 0.7	0.95 ± 0.5	1.07 ± 0.6	1.22 ± 0.4	1.53 ± 0.4
	Group C	1.13 ± 0.9	0.46 ± 0.6	0.54 ± 0.7	0.76 ± 0.6	0.85 ± 0.4	1.03 ± 0.5	1.17 ± 0.5	1.48 ± 0.4
PD	Group T	2.46 ± 0.5	1.63 ± 0.6	1.28 ± 0.6	1.48 ± 0.4	1.61 ± 0.5	1.75 ± 0.3	1.84 ± 0.4	2.17 ± 0.4
	Group C	2.32 ± 0.6	1.39 ± 0.5	1.02 ± 0.6	1.23 ± 0.6	1.39 ± 0.5	1.71 ± 0.4	1.83 ± 0.4	2.11 ± 0.3
BI	Group T	0.95 ± 0.9	0,65 ± 0.7	0,35 ± 0.5	0.5 ± 0.5	0.69 ± 0.4	0.88 ± 0.3	1.03 ± 0.3	1.23 ± 0.2
	Group C	0.79 ± 0.6	0,59 ± 0.6	0,26 ± 0.5	0.44 ± 0.4	0.6 ± 0.4	0.81 ± 0.4	0.95 ± 0.4	2.19 ± 0.3
GI	Group T	1.05 ± 0.4	0.98 ± 0.5	0.79 ± 0.4	0.92 ± 0.3	1.03 ± 0.3	1.22 ± 0.3	1.38 ± 0.3	1.77 ± 0.2
	Group C	0.94 ± 0.8	0.89 ± 0.5	0.75 ± 0.4	0.86 ± 0.6	0.96 ± 0.4	1.27 ± 0.4	1.4 ± 0.3	1.73 ± 0.2

BI = bleeding index; GI = gingival index; PD = probing depths; PI = plaque index.

implants and the other receiving ITI (Straumann) implants. After the two interforaminal implants were placed, ball abutments were seated and a soft reline was completed for the mandibular denture. Two weeks postoperatively, the mandibular complete dentures received a hard reline and the appropriate matrices were attached. Standardized radiographs were made to monitor marginal bone resoption. After 1 year, no implants were lost in either group and there were no significant differences in marginal bone loss (0.28 mm), peri-implant parameters or prosthodontic maintenance during the study.

One of the most important measurements of success is the average marginal bone resorption. After 7 years of postoperative evaluation, the mean marginal bone loss was 1.31 ± 0.2 mm for all patients. In addition, the average annual bone loss after the first year did not exceed 0.2 mm for either group. Other authors have found similar results over 5 years. Visser et al.[35] reported an average of 1.6 ± 1 mm of marginal bone resorption after 5 years for patients with mandibular two-implant overdentures while Meijer et al.,[36] in a 10-year clinical trial, reported 0.7 mm of bone loss in the first year and an annual bone loss of <0.2 mm for all subsequent years. The differences in bone resorption in the first year may have resulted from differing bone quality, occlusal forces, opposing dentition/denture and the type of implants used in the studies. In a 10-year follow-up of unsplinted mandibular implant overdentures, opposing maxillary complete dentures, Ma et al.[27]

All implants in this study were placed in the canine regions of the mandible. It is well known that the bone density of the anterior mandible is of higher quality when compared with other areas of the mouth. This higher bone density results in higher implant torque values, better primary stability, and increased success of implants.[37] Turkyilmaz et al.,[38] determined a relationship between bone density, insertion torque, and implant stability at the time of implant placement. One hundred eight patients were treated with 230 Brånemark implants. Preoperative evaluation was completed using a computerized tomography machine (assessing Hounsfeld Units). At the time of implant surgery, the maximum torque values were recorded and RF measurements were made. There were 80 anterior mandibular sites, 50 posterior mandibular sites, 45 anterior maxillary sites, and 55 posterior maxillary sites. The mean bone density values were as follows: 928 ± 220 Hounsfeld Units (HU) (anterior mandible), 669 ± 194 HU (posterior mandible), 732 ± 163 HU (anterior maxilla), 459 ± 108 HU (posterior maxilla). They found positive, statistically significant correlations between higher bone density, increased insertion torque and improved ISQ values.

In this study, both groups of implants had an average initial ISQ value of approximately 75 units. This is comparable to a study by Payne et al.,[34] which reported an average primary stability of 75 ISQ units for 24 Southern implants. However, in this study, the ISQ values decreased slightly in the first 3 months, and increased from month 3 to month 18, which is consistent with the data reported by Friberg et al.[39] The marginal bone remodeling that occurs during the first several months may explain the decreased ISQ values, because the distance of the RFA transducer to the first bone contact affects RFA measurements.[40] Overall, it seems that bone remodeling positively affected implant stability and counteracted the effect of marginal bone loss long-term.

The peri-implant parameters (PI, PD, BI, GI) showed no significant differences between the test and control groups during the 7 years of the study. This data is consistent with that from other studies in which soft tissue changes were measured.[41,42] The patients in the test group showed decreased PI values from baseline to 1 year, indicating good oral hygiene. However, the mean PI values increased for both groups from year 1 to year 7. The mean PI values for the control group were lower than those of the test group. It has been considered that this difference might have resulted from the control group receiving the ball abutments at the 3-month visit, thus having less time for plaque accumulation in the oral environment. The excess peri-implant mucosa was immediately removed after implant placement, thus limiting the mean PD values. The limited amount of soft tissue around the ball/healing abutments also allowed for easier implant-level RFA. The mean PD values decreased significantly for both groups in the first 6 months, likely because of gingival shrinkage as a result of healing.

CONCLUSION

This study suggests that a 1-week early loading protocol for two unsplinted mandibular implants with TiUnite surface supporting a mandibular overdenture may be a safe treatment option for the edentulous mandible.

ACKNOWLEDGMENTS

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